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VIA ELECTRONIC MAIL

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Re: *United States v. Gilbert Ghearing*, Case No. 2:19-cr-00010 (MDTN) – Revised Disclosure

NOTICE OF EXPERT OPINION TESTIMONY

The United States provided an expert disclosure on July 14, 2021. This is a revised disclosure.

In compliance with Federal Rule of Criminal Procedure 16(a)(1)(G), the United States provides notice that the following persons may be called to provide expert testimony at the trial of this case. Certain witnesses identified below may offer testimony under Federal Rules of Evidence 602 and 701 as fact witnesses, and they may offer lay opinion as appropriate. In addition, witnesses identified below may be called upon to offer relevant opinion testimony under Federal Rule of Evidence 702 and 703, as appropriate. Thus, the government is disclosing this information out of an abundance of caution in case the proffered testimony might arguably fall under Rule 702, or if a witness is called upon to offer relevant opinion testimony.

The United States will provide the curriculum vitae (CV) for each witness identified below.

David A. Edwards, M.D. PhD

David A. Edwards, MD PhD will provide expert testimony in the field of medicine and pain management based on his educational background, training, and experience, as detailed in his CV, which is attached and incorporated by reference. He is an Associate Professor of Anesthesiology and Neurological Surgery and Chief of the Division of Pain Medicine at

Vanderbilt University Medical Center. He oversees and personally cares for patients in several specialty clinics that treat patients for cancer-related pain, chronic pain, operative pain, and high-risk patients admitted to the hospital with pain or substance use disorder. His research is focused on the transitional care of patients in the perioperative period, and the functional recovery of postoperative patients.

Dr. Edwards is board certified in Pain Medicine and Anesthesiology. Dr. Edwards specializes in adult anesthesiology, and adult and pediatric pain medicine. He is an expert in acute and chronic pain and in the use of pain relief and analgesics. He has particular knowledge of opioids and cannabinoids and how they affect the nervous system.

Dr. Edwards has not testified in a criminal trial before. Dr. Edwards did not write a report. Dr. Edwards' testimony is expected to cover the usual course of professional practice as it pertains to Pain Medicine. Dr. Edwards' testimony is expected to provide an overview of pain management and treatment options, including:

- explanation of pain management treatment;
- various forms of pain management treatment;
- diagnostic techniques;
- identification and explanation of controlled substances, and schedules;
- how opioids and other controlled substances work in the body;
- addictive risks of controlled substances including oxycodone, hydrocodone, alprazolam, and others;
- opioid pain management treatment, when it should be used, the risks, and side effects;
- the doctor / patient relationship;
- physical examinations and the need to request and verify the previous medical history of a patient when dealing with controlled substances;
- education and informed consent;
- dangers involved with prescribing certain combinations of controlled substances;
- importance of the controlled substance monitoring;
- documentation;
- risks and signs of opioid use disorder and associated courses of action;
- laws and guidelines governing prescribing and pain management

Dr. Edwards has not reviewed any of the evidence from this case. His testimony will focus on the usual course of professional practice in the area of pain management based on his educational background, training, and experience. He may also rely on reference to the Tennessee Chronic Pain Guidelines, Tennessee Pain Clinic Guidelines, Tennessee Board of Medicine standards of conduct, applicable Tennessee Code Annotated sections on pain treatment and pain management clinics, medical treatment, and opioid prescribing, Controlled Substances Act and regulations governing DEA registrations, American Medical Association Code of Medical Ethics, CDC and FDA guidelines, the Code of Federal Regulation, opioid treatment tools, as well as respected, peer-reviewed, medical and scientific literature. He has lectured extensively on these

topics, as demonstrated by his CV. His testimony will serve the purpose of background education to the jury on pain medicine.

Carl Christensen, M.D.

Dr. Christensen will provide expert opinion testimony based on his educational background, training, and experience, as detailed in his CV, which is attached and incorporated by reference. Dr. Christensen is a specialist in the field of addiction and pain medication management, and like Dr. Ghearing, is an OB/GYN.

The United States anticipates that Dr. Christensen will testify about the usual course of the professional practice of medicine, including the importance of reaching the correct diagnosis and offering the correct treatment for each individual patient. He will also discuss the signs and dangers of addiction.

Dr. Christensen conducted a file review for the patients listed in the indictment.¹ Dr. Christensen will provide testimony and expert opinion in connection with that patient file review. The United States expects Dr. Christensen to testify specifically about Dr. Ghearing's prescribing practices, and how Dr. Ghearing's conduct relates to the usual course of professional practice. Furthermore, the Government anticipates Dr. Christensen to testify that the conduct and prescriptions at issue were outside the usual course of professional practice, not for legitimate medical purposes. His methods, sources, and findings are identified in his reports, which have been previously disclosed to counsel for defendant in March and April 2020 and July 2021. He is in the process of reviewing the reports again and we will provide any revisions, to the extent there are any. The United States anticipates that Dr. Christensen will provide testimony consistent with the findings in these reports. The United States reserves the right for Dr. Christensen to supplement the reviews in light of the parties seeking to agree on one set of medical records as joint exhibits, in light of the possibility defense produces other records.

In addition to providing expert opinion testimony related to the patient file review, Dr. Christensen may present testimony on the following general topics based on his specialized education, training, and experience, and in particular, in addition:

- An overview of the doctor-patient relationship;
- The legitimate medical purposes of the drugs at issue in this case, such as oxycodone, muscle relaxers, and benzodiazepines, including testimony about drug interactions, contraindications, potentiating effect, and the prescribing of therapeutic versus non-therapeutic amounts;
- Dr. Christensen will also testify about the risks associated with prescribing opioid drugs, and why it is necessary to prescribe controlled substances only for a legitimate medical

¹ He also reviewed other patient medical records, PDMP/CSMD, and the undercover visits. In light of the decision in *United States v. Ruan*, we might elect to solicit testimony regarding his opinion of these materials.

purpose in the course of professional practice in order to mitigate those risks. For example, he will testify about:

- Various studies documenting the dangers of opioid usage, including the “Boehnert” study, the “Dunn” study, the “Gomes” study, and The Tennessee Chronic Pain Guidelines and the CDC Guidelines.
- He will testify about the dangers (including death and addiction) as well as the ineffectiveness of prescribing opioids, benzodiazepines, and muscle relaxers. Dr. Christensen will refer to the 2016 Food and Drug Administration black box warning regarding the serious dangers of concurrently prescribing opioids and benzodiazepines.
- The risk of physical dependence and withdrawals.
- The risk of addiction, particularly opioid addiction, the signs of addiction, the impact of addiction on the patient and the patient’s friends and family, treatment of addiction, and the dangers of overdose and death from drug misuse and abuse.
- The potential for misuse of controlled substances, and their addictive properties. He will further testify about a physician’s duty to watch for signs of abuse, addiction, and diversion in the usual course of professional practice, and the warning signs and diagnostic tools prescribers use in the usual course of professional practice to determine whether a patient is suffering from addiction.
- Other risks and side effects of opioid use.
- Long acting versus short acting opioids.
- The number of overdoses in carefully managed family practice and pain management practices is normally extremely low. However, when the physicians in charge of treatment abdicate their responsibilities to honestly convey the risks associated with any given treatment, overdoses can occur.
- The United States expects that Dr. Christensen will provide expert opinions as to the Dr. Ghearing’s prescribing and dispensing practices, based on his review of the patient files and records, and the Tennessee Controlled Substance Monitoring Database (CSMD) including:
 - The controlled substances prescribed by the defendants to the patients listed in the indictment were not prescribed in the usual course of professional practice for a legitimate medical purpose.
 - Dr. Christensen will testify consistent with the disclosed reports regarding his analysis of individual patient files. In addition, he will incorporate the patient’s

history, as documented by the defendants' medical files and CSMD, in reaching his conclusion that the charged prescriptions were not written for a legitimate medical purpose in the course of professional practice.

- The CSMD data for Dr. Ghearing.

In reaching his conclusions, Dr. Christensen has relied on his knowledge, training, skill, and experience as well as other sources as listed in his reports. Dr. Christensen reserves the right to supplement his respective opinions as necessary to address the issues raised in this case. He may review additional material prior to and during trial to further ensure the opinions remain accurate and complete.

James Hischar, DEA Supervisory Diversion Investigator

James Hischar's qualifications are described on his attached CV and are incorporated by reference. Mr. Hischar did not prepare a report. Mr. Hischar may testify, based on his knowledge, training, skill, and experience, about the following:

- The Controlled Substances Act, including the various schedules, the reasons each drug is scheduled, and the types of drugs included under each;
- DEA registrations, how a doctor obtains one and the rules and regulations governing them;
- The defendant's DEA registration;
- What information a valid prescription must contain and that to be authorized a prescription must be for a legitimate medical purpose and in the usual course of professional conduct;
- The Modus Operandi evidence that law enforcement look for in controlled substances prescribing patterns. These include, for example, dangerous drug combinations such as opioids combined with benzodiazepines, and the numbers of prescriptions and amounts of pills;
- He may offer testimony about methods commonly employed by physicians/medical personnel to prevent patients from diverting prescription drugs;
- He may testify about common practices of drug seeking patients and the methods patients use to circumvent drug screening and pill counts and the common practices that physicians employ to prevent patients from obtaining controlled substance prescriptions that are not medically necessary or outside of the usual course of professional practice.
- Use of ARCOs and Prescription Monitoring Database Program data, including what data it captures, who inputs the data, and how it can be used by law enforcement in investigating prescribing and dispensing patterns.

Stephen Quindoza, Fraud Investigations Team Lead, UPIC

Mr. Quindoza's qualifications are described in his attached CV and incorporated by reference. Mr. Quindoza is presently the Fraud Investigations Team Lead at SafeGuard Services, LLC, a company responsible for supporting the Unified Program Integrity Contractors ("UPICs") for the Northeast and Southeast geographic regions for the Medicare and Medicaid programs. The UPICs are responsible for performing fraud, waste, and abuse detection and deterrence activities

for the Medicare and Medicaid programs on behalf of the United States Department of Health and Human Services. The witness has approximately 35 years of experience working as a Medicare contractor, where his responsibilities have included fraud investigations, payment processing of Medicare claims, and Medicare compliance. Mr. Quindoza has testified in more than 20 previous trials during his time supporting the Medicare and Medicaid programs.

The witness did not write a report. The information to be elicited from Mr. Quindoza at trial, includes:

- The qualifications and experience summarized in his resume (attached and incorporated by reference)
- The structure of Medicare, including the purpose of the health insurance program and eligibility.
 - Medicare is a form of federal assistance that provides health insurance benefits to individuals who are at least 65 years old, and to the disabled;
 - Medicare is funded by United States taxpayers;
 - Medicare is administered by the Centers for Medicare and Medicaid Services (“CMS”), and that CMS uses contractors to run the Medicare program;
 - Medicare uses entities known as “MACs”, Medicare Administrative Contractors, to process and pay Medicare claims; and
 - Part B of the Medicare program covers office visits and ancillary services; Part D covers prescriptions for medicine.
- Medicare is a trust-based system that relies on the honesty and integrity of its providers.
 - Medicare providers, including physicians, must agree to follow the rules and regulations of the program.
 - The Medicare program offers training and written guidance concerning these rules and regulations, many of which are publicly available.
- All claims submitted to Medicare for payment must be for reasonable and medically necessary items and services.
- Medicare reimburses providers for certain physician office visits,
- Medicare, through CMS and its contractors, will not pay claims for services (under Parts B and D) if it is determined the service was not rendered in accordance with program rules.
- Overview of the Medicaid program and rules and regulations

Mr. Quindoza will serve as a custodian of records for Medicare claims data and enrollment. Thus, the government intends to admit through this witness Medicare application(s) and Medicare claims data. Moreover, the witness may testify about the defendant’s patient population, diagnosis codes, and billing patterns as it relates to Medicare and Medicaid, and may prepare summary charts of the same. The defendant received several forms of data as part of discovery, including Part D data and TennCare/Medicaid pharmacy and clinic billing data, and Part B underlying data which was previously disclosed to counsel in July 2021. The United States will provide summary charts in advance of trial.

Mr. Quindoza’s testimony will be based on his knowledge, training, skill, and experience. His testimony is relevant and admissible to the manner and means by which defendant unlawfully

distributed controlled substances, and engaged in a scheme to defraud Medicare and Medicaid. Testimony explaining how the Medicare and Medicaid program works, and why federal health care programs do not pay claims for unnecessary services/services provided outside the usual course of professional practice without legitimate medical purposes will assist the jury in determining the defendant's guilt on the charged crimes. Lastly, the witness's testimony is relevant to show the financial motivation behind the defendant's treatment protocol.

Johanna Sullivan, PharmD, Director of Clinical Operations, MEDIC

Ms. Sullivan's qualifications are described in her attached CV and incorporated by reference. Ms. Sullivan is the Director of Clinical Operations, Investigations Medicare Drug Integrity Contract (MEDIC) with Qlarant. Ms. Sullivan has been associated, directly and indirectly, with the Medicare program for over 25 years, with prior experience in her role as a pharmacist for over a decade. She has worked primarily for Medicare contractors in compliance reviews for Medicare Part D. Ms. Sullivan is also responsible for outreach activities related to fraud and abuse, support and education, and coordinating and sharing information with the Centers for Medicare and Medicare Services and law enforcement agencies.

The United States anticipates that Ms. Sullivan will provide overarching and background testimony concerning the Medicare Part D program. The United States further anticipates that Ms. Sullivan will provide more focused testimony about the Medicare prescription drug coverage, Medicare funding, claims processing, and payment. Ms. Sullivan will also discuss and explain how the Medicare billing system would and did process, adjudicate, and pay various claims, including claims and claims' data summaries for prescriptions written by Dr. Ghearing, and the Medicare program's rules and regulations related thereto. Ms. Sullivan may discuss, authenticate, and introduce the following types of documents:

- Medicare rules, regulations, and guidance;
- Documents submitted to Medicare or a contractor related to a prescription written by Defendant;
- Claims submission and payment procedures for Medicare; and
- Claims data related to prescriptions written by Defendant.

The Government anticipates Ms. Sullivan will testify concerning the application of Medicare's rules and regulations to prescriptions written by Defendant. This testimony would include:

- whether Medicare would, in various scenarios, knowingly pay for certain types of prescriptions;
- that Medicare would not pay for a prescription not prescribed for a legitimate medical purpose or not in the usual course of professional practice.

Ms. Sullivan may testify about her analysis of claims, prescriptions, and data associated with Dr. Ghearing, including:

- Patterns from the prescription data, including the percentage and volume of different prescriptions, long acting versus short acting opioid prescriptions, numbers by diagnosis code, frequency of certain diagnosis codes
- Payment patterns
- Volume of Dr. Ghearing patients at pharmacies
- Percentages of Dr. Ghearing's patients on opioids, or opioids and other controlled substance combinations

Ms. Sullivan's opinions will be based on her knowledge, training, skill, and experience working with the Medicare program including its rules and regulations, as well as her review and analysis of documents and claims data, which have been provided or made available as discovery to Defendant in this case. Ms. Sullivan wrote a report that is included with this disclosure, and relied on sources as cite therein. Ms. Sullivan reserves the right to supplement her respective opinions as necessary to address the issues raised in this case. She may review additional material prior to and during trial to further ensure the opinions remain accurate and complete. Ms. Sullivan may prepare summary charts and they will be made available before trial.

Aaron Butler, Director of Policy, Division of TennCare

Aaron Butler's qualifications are described on his CV, attached and incorporated by reference. The United States anticipates that Mr. Butler will provide overarching and background testimony concerning TennCare (Tennessee's Medicaid program).

He may testify about the rules for TennCare Managed Care Organizations, including how Managed Care works in Tennessee and with the TennCare program. He may testify about how a physician enrolls with TennCare and then with a managed care organization and what is required in order to bill claims for services provided to a beneficiary. For example, a primary care physician must be contracted with the managed care organization. He may testify about what TennCare pays for and what is deemed medically necessary, how they pay claims, and requirements to participate. He may testify about the managed care contracts and terms, the defendant's enrollment in TennCare, and that TennCare, through the managed care plans, does not pay for medically unnecessary services, and other rules of the program.

The United States further his anticipates that Mr. Butler will provide testimony about Medicaid prescription drug coverage and Medicaid funding. The United States anticipates Mr. Butler testifying about how prescriptions are paid by TennCare through its pharmacy benefit manager, Magellan, and Magellan's contract with TennCare during the relevant indictment timeframe. The witness will explain how Magellan worked, what a pharmacy benefit manager means, and provide testimony about the prescription drug coverage, funding, claims processing, and payment through Magellan. He may discuss or seek to introduce:

- TennCare rules, regulations, and guidance; including the TennCare Administrative Rules;
- Documents submitted to TennCare or a contractor related to a prescription written by Defendant;
- TennCare Provider Participation Agreement;

- TennCare's contracts with its managed care organizations;

The Government anticipates Mr. Butler will testify concerning the application of TennCare's rules and regulations to prescriptions. This testimony would include:

- whether TennCare would, in various scenarios, knowingly pay for certain types of prescriptions;
- that TennCare would not pay for a prescription not prescribed for medically necessary reasons or not in compliance with state and federal laws, including where not for a legitimate medical purpose or not in the usual course of professional practice.

Mr. Butler's opinions will be based on his knowledge, training, skill, and experience working with the TennCare program including its rules and regulations, as well as his review and analysis of rules and regulations, which have been provided or made available as discovery to Defendant in this case. The witness did not write a report.

Joshua T. Bazuin, Medicaid Informatics Director, TennCare

Joshua Bazuin's qualifications are described on his CV, attached and incorporated by reference. The United States anticipates that Mr. Bazuin will discuss and explain how TennCare claims were processed, adjudicated, and paid. Mr. Bazuin will serve as a custodian of records for TennCare related claims data, and may discuss, authenticate, and introduce the following types of documents:

- Documents submitted to TennCare or a contractor related to prescriptions written by Defendant;
- Claims submission and payment procedures for TennCare;
- Claims data related to prescriptions written by defendant;
- Claims data associated with patients of the defendant; and
- Claims data related to visits with the defendant.

Mr. Bazuin's opinions will be based on his knowledge, training, skill, and experience working with the TennCare program, as well as his review and analysis of documents and claims data, which have been provided or made available as discovery to Defendant in this case.

Tina M. Hawkins, PharmD, Senior Director, Magellan Rx Management

Tina Hawkins' CV is attached and incorporated by reference. Ms. Hawkins is the Senior Director in Clinical Account Services of Magellan Rx Management (Magellan). The United States anticipates that Ms. Hawkins will explain Magellan's contract with TennCare during the relevant indictment timeframe. Magellan was the pharmacy benefit manager for TennCare and responsible for the payment of claims. Ms. Hawkins will explain how Magellan worked, what a pharmacy benefit manager means, and provide focused testimony about the prescription drug coverage, funding, claims processing, and payment through Magellan. The Magellan witness may discuss:

- Documents submitted to Magellan related to prescriptions written by Defendant;
- Claims submission and payment procedures for Magellan; and
- Claims data related to prescriptions written by Defendant.

The Government anticipates Ms. Hawkins may testify concerning the application of Magellan and TennCare's rules and regulations to prescriptions. This testimony would include:

- whether Magellan, per TennCare rules, would, in various scenarios, knowingly pay for certain types of prescriptions;
- that Magellan, per TennCare rules, would not pay for a prescription not prescribed for a legitimate medical purpose or not in the usual course of professional practice.

Ms. Hawkins' opinions will be based on her knowledge, training, skill, and experience working with the Magellan program including its rules and regulations, as well as her review and analysis of documents and claims data, which have been provided or made available as discovery to Defendant in this case. Ms. Hawkins did not write a report. Magellan is no longer the pharmacy benefit manager for TennCare.

Pete Phillips, PharmD, Director, Controlled Substance Monitoring Database, Tennessee Department of Health

Mr. Phillips' CV is attached and incorporated by reference. He is the Director of the Controlled Substances Monitoring Database Program at the Tennessee Department of Health.

Mr. Phillips oversees the Controlled Substances Monitoring Database ("CSMD") program in Tennessee. Based on his education, training, knowledge, skill, and experience, he will testify about the program, how data is inputted, laws and regulations regarding the CSMD in Tennessee, and how the database reports are generated. The United States may seek to admit relevant CSMD reports through Mr. Phillips. Mr. Phillips did not prepare a report.

Lisa Livingston, TBI Nurse

Lisa Livingston's CV is attached and incorporated by reference. Ms. Livingston is a nurse employed at the Tennessee Bureau of Investigation. Ms. Livingston's testimony may ultimately be lay testimony, and not be admitted as expert testimony, but we disclose her as a witness out of an abundance of caution. Ms. Livingston will testify regarding the contents of certain patient medical records for patients in the indictment, prescriptions, as well as certain portions of the CSMD for patients in the indictment.

Nurse Livingston may testify about the claims, prescriptions, and data associated with Dr. Ghearing, including:

- Patterns from the claims data and prescription data, including percentages and volumes

- Numbers Dr. Ghearing's patients on opioids, or opioids and other controlled substance combinations

The basis for Ms. Livingston's testimony is from her review of discovery materials, to include, patient files and documents from search warrants, CSMD reports, prescriptions obtained from pharmacies, emails, and claims data. Ms. Livingston may also prepare summary charts based on her review of these materials. The summary charts will be provided in advance of trial. Ms. Livingston did not prepare a report.

The defendant received the underlying materials as part of discovery.

REQUEST FOR RECIPROCAL DISCOVERY

The United States requests, pursuant to Rule 16(b)(1)(A) and (B), that the defendant permit the United States to inspect and copy or photograph:

- (1) Books, papers, documents, data, photographs, tangible objects, buildings or places, or copies or portions of any of these items, which are within the possession, custody, or control of the defendant which the defendant intends to introduce as evidence-in-chief at the trial; and
- (2) Any results or reports of physical or mental examinations and of scientific tests or experiments, or copies thereof within the possession or control of the defendant which the defendant intends to introduce as evidence-in-chief at the trial or which were prepared by a witness the defendant intends to call at trial when the results or reports relate to his or her testimony.

In return for our compliance with Rule 16(a)(1)(G), we hereby request a written summary of any testimony the defendant intends to use as evidence at trial under Federal Rules of Evidence 702, 703, or 705. The summary should describe the witness's opinions, the bases and reasons for these opinions, and the witness's qualifications.

Please notify us as soon as possible if such documents, reports, etc., are available so that appropriate arrangements can be made to receive them.

This is an ongoing, continuing request, so that materials which are discovered in the future should be brought to the United States' attention so that appropriate arrangements for disclosure may be made at that time. The United States will likewise do the same.

If necessary, the United States will timely revise and update this disclosure and/or reports as referenced herein and will advise you in advance if we intend to do so. We would appreciate a discussion on any concerns or objections in advance of any motions practice to give us the

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opportunity to potentially reach an agreed resolution on any disagreements prior to seeking the intervention of the Court. We will likewise extend the same courtesy upon receipt of Dr. Ghearing's disclosures.

Sincerely,

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